APR 2 7 2004

K040067

510(k) SUMMARY

SUBMITTER INFORMATION

A. Company Name: Spectranetics Corporation, Inc.

B. Company Address: 96 Talamine Court
Colorado Springs, Colorado 80907

C. Company Phone: 719-633-08333 / 1-800-633-0960

D. Company Facsimile: 719 442 2248

E. Contact Person: Adrian Elfe
Vice President
Quality Assurance & Regulatory Affairs Compliance

DEVICE IDENTIFICATION

A. Device Trade Name: CLiRpath Excimer Laser Catheter

B. Device Common Name: Laser Catheter

C. Classification Name: Catheter, Peripheral, Atherectomy

D. Device Class: Class II (per 21 CFR 870.4875)

E. Device Code: MCW

IDENTIFICATION OF PREDICATE DEVICES

The Safe Cross Radio Frequency Total Occlusion Crossing System (IntraLuminal Therapeutics, Inc.), which received market clearance under 510(k) K031842, is the primary predicate device. Other predicate devices include: Rotablator Rotational Angioplasty Systems (Heart Technology, Inc.) cleared under 510(k) applications K901206 and K933328, the Frontrunner CTO Catheter (LuMend, Inc.) cleared under 510(k) K023114, and the Silverhawk Peripheral Catheter System (Foxhollow) cleared under 510(k) K024243.

DEVICE DESCRIPTION

Spectranetics laser atherectomy catheters consist of a bundle of optical fibers, encased within medical grade tubing. The optical fibers conduct ultraviolet laser light (excimer laser light at 308 nm) from a source to the tip of the catheter. The catheter is inserted into a patient's vasculature along the length of a previously inserted medical guidewire, allowing the attending physician to deliver laser energy targeted to a lesion (blockage) in the blood vessel. Both over-the-wire and rapid-exchange catheter configurations are available. Laser energy impinged on a blockage ablates, or debulks, the lesion material thus opening the vessel, permitting placement of devices used in vascular interventions.

Spectranetics laser catheters are supplied in several models having tip diameters between 0.9 mm and 2.5 mm, appropriate for interventional use in peripheral arteries. Both over-the-wire and rapid exchange models are available.

INTENDED USE

CLiRpath™ catheters are intended for use in ablating a channel in totally occlusive peripheral vascular disease (including the superficial femoral, popliteal and infrapopliteal arteries), for enhancing the potential for limb preservation.

COMPARISON TO PREDICATE DEVICES

Spectranetics laser catheters for peripheral use are substantially equivalent in form, fit, and function to four (4) predicate devices, which have received market clearance under section 510(k) rules.

Each of the devices is a catheter, i.e. a piece of tubing with a working length of approximately 100 cm, and a diameter between 0.9 mm and 6.0 mm. The catheters communicate mechanical and/or radiant energy to an occlusion within a patient's arteries in the lower limbs. Communicated energy disrupts occlusive material, such as arterial plaque, and permits its removal either when the catheter is withdrawn, or via the patient's endoreticular system. The pathway opened by each of the devices facilitates subsequent placement of other devices and interventions.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Biocompatibility of component materials and finished CLiRpath devices has been confirmed in accord with the ISO 10993 series of standards, Biological Evaluation of Medical Devices. Spectranetics conducts and maintains valid ethylene oxide sterilization processes in accord with ISO 11135, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization. Package integrity is initially validated, and, in addition, visually verified for 100% of Spectranetics devices prior to transfer to finished goods inventory.

CLiRpath device integrity and functionality were qualified and/or validated using samples produced under routine manufacturing conditions. All excimer laser CLiRpath catheter models meet or exceed both Spectranetics in-house requirements, and requirements listed in ISO 10555-1, Sterile, Single-use Intravascular Catheters – Part 1: General Requirements.

CLINICAL STUDIES

Forty-seven (47) patients with distal peripheral arterial disease were enrolled at investigational sites in the United States, Germany, and Belgium. The CLiRpath step by step excimer laser catheter procedure successfully crossed 79% of lesions recalcitrant to crossing with conventional guidewires. Overall procedural success was achieved in 72% of the cases, and straight-line blood flow was re-established to the foot in 79% of the cases. Serious adverse events associated with CLiRpath step by step treatments were more rare than those observed during a larger registry study of laser atherectomy in the arteries of the legs.

CONCLUSION

Human clinical studies verified the safety and performance characteristics for Spectranetics CLiRpath excimer laser catheters for use in the treatment of peripheral arterial disease. In vitro laboratory tests, as well as qualification and validation studies, have confirmed that CLiRpath catheters meet manufacturing and design specifications. All of these data combined establish substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2004

Spectranetics Corporation
c/o Mr. Neil Burris
Senior Clinical Data Services Analyst
96 Talamine Court
Colorado Springs, CO 80907-5186

Re: K040067
Trade Name: CLiRpath Excimer Laser Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MCW
Dated: March 23, 2004
Received: March 24, 2004

Dear Mr. Burris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040067

7. Statement of Indication for Use

Indication for Use

510(k) Number (if known): K040067

DRL 4/26/04

Device Name: Spectranetics CLiRpath™ Excimer Laser Catheters

Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions cannot be crossed with standard guide wires.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachmann

(Division Sign-Off)
Division of Cardiovascular Devices

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